Disclaimer!

- This is not a consensus statement this is a draft summary of the presentations that will require further review by the participants to finalise a consensus statement.

New Techniques to Detect Oncogenic Viruses

- New techniques should only be routinely introduced if they are robust, can be validated to ICH criteria and have the potential to add new safety information.
- Other assays or experiments may be of value in providing background information.

Assays That May Be Considered for New Cell Substrates

- Redundant PCR for herpesviruses and polyomaviruses has potential merit.
- RDA has too many problems to be considered as a routine technique but could have value as an invesigational tool.
- PERT assay has become established as a useful broad screening assay for cell substrates but it has limitations when examining virus master seeds.

DNA Transfection

- Infectivity of small DNA viruses via DNA is a theoretical problem but should be overcome by adequate shearing of the DNA or reduction in DNA level.
- Small DNA viruses often contain multiple transforming functions within a short sequence which requires shearing < 600pb to inactivate.

Retrovirus Issues

- Retrovirus elements are constituents of all vertebrate cells and have been identified in insect and yeast cells.
- Some endogenous viruses are replication competent and may infect cells of other species.
- Infectivity assays should be used where possible but often target cells for infectivity are not known.

Retrovirus Issues 2

- Pseudotype formation between vaccine viruses and lentiviruses does not appear to be an issue, but requires further study for gamma and alpha retroviruses.
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- Induction assays should form part of the characterisation of new ell substrates.

SV40 and Polyomaviruses

- The detection of SV40 sequences in certain human tumours particularly mesotheliomas, brain tumours and osteosarcomas has been recorded by several labs (>50 reports). There are 5 reports of negative data for these tumour types.
- There is a dichotomy for lymphomas. Some laboratories have recorded ~40% positivity others have been uniformly negative.

SV40 and Polyomaviruses

- There is a constant low level of seopositivity and titre to SV40 across age cohorts.
- In ELISA assays adsorption by BK VLPs may account for this antibody but some anomalies exist.
- The presence & role of SV40 in human populations requires further investigation.
- The possibility that SV40 may have come from contaminated primary cells emphasises the value of using well characterised cell lines.